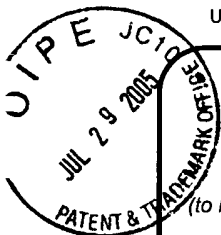


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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/955,259	
	Filing Date	September 12, 2001
	First Named Inventor	Nestor Annibali
	Group Art Unit	1636
	Examiner Name	D. A. Lambertson
Attorney Docket Number	52071.4	
Total Number of Pages in This Submission (excluding references)	9	

ENCLOSURES (check all that apply)

<input checked="" type="checkbox"/> Deposit Account 07-1850 Authorization <input checked="" type="checkbox"/> Postage Paid Return Postcard <input type="checkbox"/> Amendment / Response <input checked="" type="checkbox"/> Fee Transmittal Letter (in duplicate) <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Petition for Extension of Time (___ months) (in duplicate) <input checked="" type="checkbox"/> Information Disclosure Statement (in duplicate) with Form PTO-1449 (2 pgs) citing 35 References <input type="checkbox"/> Express Mail Label No. <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) In/Formal ___ Sheets with Submission of Drawings Transmittal <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) ___	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): 35 References		
<table border="1"> <tr> <td>Remarks</td> <td></td> </tr> </table>			Remarks	
Remarks				

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Squire, Sanders & Dempsey L.L.P. Brian S. Boyer, Ph.D. Reg. No. 52,643
Signature	
Date	July <u>27</u> , 2005

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FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 180.00

Complete if Known

Application Number 09/955,259
Filing Date September 12, 2001
First Named Inventor Nestor Annibali
Examiner Name D. A. Lambertson
Art Unit 1623
Attorney Docket No. 52071.4

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money ☐ Other ☐ None
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Deposit Account Number 07-1850

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1)

(\$)

2. EXTRA CLAIM FEES

Total Claims	Independent Claims	Multiple Dependent	Extra Claims	Fee from below	Fee Paid
		0		0	

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1202	18	2202	9	Claims in excess of 20	
1201	84	2201	42	Independent claims in excess of 3	
1203	280	2203	140	Multiple dependent claim, if not paid	
1204	84	2204	42	** Reissue independent claims over original patent	
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent	

SUBTOTAL (2)

(\$).00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	205	Extension for reply within second month	
1253	950	2253	465	Extension for reply within third month	
1254	1,480	2254	725	Extension for reply within fourth month	
1255	2,010	2255	985	Extension for reply within fifth month	
1401	330	2401	160	Notice of Appeal	
1402	330	2402	160	Filing a brief in support of an appeal	
1403	290	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,330	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	180
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

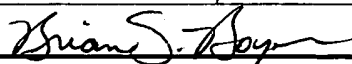
*Reduced by Basic Filing Fee Paid

SUBTOTAL (3)

(\$180.00)

SUBMITTED BY

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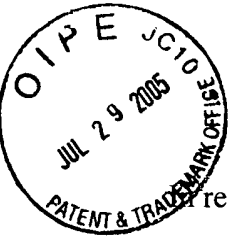
Name (Print/Type)	Brian S. Boyer, Ph.D.	Registration No. Attorney/Agent)	52,643	Telephone	(415) 954-0200
Signature				Date	July 27, 2005

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Pre Application of:

Examiner: D. A. Lambertson

Nestor Annibali

Serial No. 09/955,259

Art Unit: 1636

Filed: September 12, 2001

Title: EXPRESSION OF A HUMAN INSULIN PRECURSOR IN
P. PASTORIS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. §§1.97-1.98**

Dear Examiner:

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and pursuant to 37 C.F.R. §§1.97-1.98, Applicant hereby notifies the U.S. Patent and Trademark Office of the references listed on the attached Form PTO-1449. Copies of the cited documents have been submitted herewith.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant reserves the right to dispute the listed documents as prior art during examination. Furthermore, Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application. The submission of this Information Disclosure Statement is not to be construed as a representation that a search has been made or that no other material information may exist. The Examiner is requested to initial the enclosed Form PTO-1449 and return a copy thereof to the undersigned.

08/01/2005 CNGUYEN2 00000022 071850 09955259


01 FC:1806 180.00 DA

The present Information Disclosure Statement is being submitted after receiving an Office Action and after three months of the filing date of the above-identified application. Therefore, the fee of \$180.00 as specified in 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) is authorized to be charged to Deposit Account No. 07-1850.

Date: July 27, 2005

SQUIRE, SANDERS & DEMPSEY L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111
Telephone (415) 954-0200
Facsimile (415) 393-9887

Respectfully submitted,


Brian S. Boyer, Ph.D.
Attorney for Applicant
Reg. No. 52,643

FORM PTO-1449 (Modified)

US DEPARTMENT OF COMMERCE

Docket No.

Application No.

US Patent and Trademark Office

52071.4

09/955,259

INFORMATION DISCLOSURE CITATION in an Application

(Use several sheets if necessary)

Applicant

Nestor Annibali

Filing Date

September 12, 2001

Group Art Unit

1636

U.S. PATENT DOCUMENTS

Examiner Initial	Ref. No.	Document Number	Date of Patent	Name	Class	Subclass	Filing Date if Appropriate
	A1	4,343,898	8/10/82	Markussen			
	A2	4,431,740	2/14/84	Bell et al.			
	A3	4,916,212	4/10/90	Markussen et al.			
	A4	5,460,954	10/24/95	Lee et al.			
	A5	5,618,913	4/8/97	Brange et al.			
	A6	5,663,291	9/2/97	Obermeier et al.			

U.S. PATENT APPLICATION PUBLICATION DOCUMENTS

Examiner Initial	Ref. No.	Document Number	Date of Publication	Name	Class	Subclass	Filing Date if Appropriate
	A7						

FOREIGN PATENT DOCUMENTS

Examiner Initial	Ref. No.	Document Number	Date of Publication	Country	Class	Subclass	Translation	
							Yes	No
	B1	0 046 979	3/10/82	EPO				
	B2	0 055 945	7/14/82	EPO				
	B3	0 195 691	9/24/86	EPO				
	B4	0 291 863	11/23/88	EPO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

	C1	Brange et al., "Monomeric insulins obtained by protein engineering and their medical implications", Nature, vol. 333, pp.679-682, 1988.					
	C2	Castellanos-Serra et al., "Expression and folding of an interleukin-2-proinsulin fusion protein and its conversion into insulin by a single step enzymatic removal of the C-peptide and the N-terminal fused sequence", FEBS Letters 378, pp. 171-176, 1996.					
	C3	Cowley et al., "Expression, purification and characterization of recombinant human proinsulin", FEBS Letters 402, pp.124-130, 1997.					
	C4	Chan et al., "Biosynthesis and periplasmic segregation of human proinsulin in <i>Escherichia coli</i> ", Proc. Natnl. Acad. Sci USA vol. 78, no. 9, pp.5401-5405, 1981.					
	C5	Chance et al., "Chemical, Physical, and Biologic Properties of Biosynthetic Human Insulin", Diabetes care, vol. 4, no. 2, pp. 147-154, 1981.					
	C6	Chance et al., "The Production of Human Insulin Using Recombinant DNA Technology and a New Chain Combination Procedure", Diabetes care 4:147; pp. 721-728, 1981.					
	C7	Chang et al., "Human insulin production from a novel mini-proinsulin which has high receptor-binding activity", Biochem. J. 329, pp. 631-635, 1998.					



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C9	Cregg et al., "Recent Advances in the Expression of Foreign Genes in <i>Pichia pastoris</i> ", Bio/Technology vol. 11, pp. 905-910, 1993.
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C11	Frank et al., "The Production of Human Proinsulin and its Transformation to Human Insulin and C-Peptide", Proceedings of the 7 th Am Peptide Chem. Symposium, pp. 729-738, 1981.
C12	Gagnon et al., "Large-Scale Process Development for Hydrophobic Interaction Chromatography, Part 1: Gel Selection and Development of Binding Conditions", Biopharm 8, pp. 21-27, 1995.
C13	Goeddel et al., "Expression In <i>Escherichia coli</i> of chemically synthesized genes for human insulin", Proc. Natnl. Acad. Sci. USA vol. 76, no. 1, pp.106 -110, 1979.
C14	Jensen et al., "Scintigraphic Studies in Rats", Diabetes, vol. 40, pp. 628-632, 1991.
C15	Katsoyannis et al., "Studies on the Synthesis of Insulin from Natural and Synthetic A and B Chains. I. Splitting of Insulin and Isolation of the S-Sulfonated Derivatives of the A and B Chains", Am. Chem. Soc. Vol. 6, no. 9, pp. 2635-2655, 1967.
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C21	Steiner et al., "The Spontaneous Reoxidation of Reduced Beef and Rat Proinsulins", Biochemistry: Steiner and Clark, vol. 60, pp. 622-629, 1968.
C22	Thim et al., "Secretion and processing of insulin precursors in yeast", Proc. Natnl. Acad. Sci. USA vol. 83, pp. 6766-6770, 1986.
C23	Veenhuis et al., "The Significance of Peroxisomes in the Metabolism of One-Carbon Compounds in Yeasts", Advances in Microbial Physiology, vol. 24, 81 pgs. 1983.
C24	Wang et al., "Studies on Receptor Binding Site of Insulin: The Hydrophobic B12VAL Can be Substituted by Hydrophilic THR", Biochem. and Molecular Biol. International vol. 39, no. 6 pp.1245-1254, 1996.
C25	Wollmer et al., "Reduction/Reoxidation Studies with Cross-Linked Insulin Derivatives", Hoppe-Seyler's Z. Physiol. Chem. Bd. 355, pp. 1471-1476, 1974.

EXAMINER	DATE CONSIDERED
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